FINDING OF NO SIGNIFICANT IMPACT

for AMENDMENTS TO 21 CFR 589 SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

§ 589.2001 Cattle Materials Prohibited in Animal Food or Feed

PROPOSED RULE

FOOD AND DRUG ADMINISTRATION September 22, 2005

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The Food and Drug Administration (FDA) is proposing to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. These materials include: 1) the brains and spinal cords from cattle 30 months of age and older; 2) the brains and spinal cords from all cattle not inspected and passed for human consumption; 3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed; 4) tallow that is derived from materials prohibited by this proposed rule unless such tallow contains no more than 0.15% insoluble impurities; and 5) mechanically separated beef that is derived from materials prohibited by this proposed rule. This measure will further strengthen existing safeguards designed to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle.

The environmental assessment (EA) prepared for the proposed rule examines the environmental consequences of the proposed action, a "total SRM prohibition, and a "no action" alternative. The EA describes major routes of disposition of cattle material prohibited in animal feed (CMPAF), provides estimates of CMPAF, discusses the effect of the proposed regulation on the rendering and processing industries and on slaughterhouse/packaging operations, and describes the effect of the proposed rule on the disposition of CMPAF. Local, State and Federal regulations on animal disposal are also discussed.

The assessment indicates that the implementation of this proposed rule would not be expected to significantly decrease the number of on-farm mortalities that are processed by renderers. No significant changes in environmental impacts from the current situation are anticipated. In addition, the incremental increase in material that will be disposed of would not be expected to significantly impact landfill or other disposal activities. We assume that disposal in landfills, incineration, and on-farm disposal would be subject to local, State, and Federal laws and regulations.

The Food and Drug Administration has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement

is not required. The evidence supporting this finding is contained in the attached EA, which was prepared under 21 CFR 25.40 of FDA's environmental regulations (21 CFR 25) and the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act.

Director,

Center for Veterinary Medicine

Attachment: Environmental Assessment, dated September 22, 2005